

JACQUELINE F. COLSON

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

9902 '99 JUN -3 AIO:33

Re: 99P-1340/CP 1; Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

On May 7, 1999, the Environmental Health Network (EHN) submitted the above-referenced petition pursuant to 21 CFR §740.1(b) to have Calvin Klein's "Eternity eau de parfum" declared misbranded. As a person who suffers disabling adverse effects from fragrance products, including "Eternity," I am writing to express my full support for the EHN petition.

Your regulations at 21 CFR §740.10(a) provide for cosmetic product warnings as follows:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning—The safety of this product has not been determined."

In addition, 21 CFR §740.1(a) requires that "a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." The conspicuousness of the warning statements required on cosmetic product packaging is addressed at 21 CFR §740.2.

As the EHN petition and the attached documentation shows, "Eternity" contains toxic ingredients as well as ingredients for which safety has not been substantiated. However, the packaging currently contains no warning label as required by your regulations. Accordingly, this product is misbranded under 21 CFR §740.10. In order to comply with the cited FDA regulations, the agency should declare "Eternity" misbranded. Further, FDA should move to require two types of labeling: 1) a label to warn of the health hazards associated with those ingredients known to be toxins, irritants, or carcinogens; and 2) a label to indicate that Eternity contains certain ingredients for which no safety data are available.

Consumers have a right to know the status of safety testing of the ingredients in products such as "Eternity." This knowledge is necessary to allow us to protect ourselves and our

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99P-1340

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May 26, 1999

families from toxic chemicals that may cause health problems. Most people are not aware that the majority of fragrance materials have only limited safety testing, nor do they know that fragrances contain chemicals that are known toxins and irritants. They wrongfully assume these products are safe to use in any setting. Consequently, they are surprised and frequently hostile when they inadvertently harm other people.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including those with asthma, migraines, chemical sensitivities, chronic fatigue, and other environmental illnesses. Because of their lower body mass, infants and children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers.

Fragrance products such as "Eternity" cause me to experience asthma, migraine headaches, dizziness, disorientation, and inability to concentrate, among other symptoms. I am a former US and state government attorney, and I have become disabled in part because of the ill effects of extremely low levels of fragrance products. My lifestyle has necessarily become limited in order to avoid perfume and other toxic chemical exposures. Not only must I avoid all fragrance products myself, I must also avoid anyone who uses them or is around others who use them. My family must shower immediately after returning from the mall or movie theater. I cannot shop or attend social functions such as concerts or movies with my family. My mail must air out on the porch to allow the mail handler's perfume to evaporate. Fragrance strips in mailers or magazines make me violently ill. I use the automated teller rather than the bank window to avoid perfume transfer from the teller's hands onto my money or deposit receipts. I cannot stay in motels or hotels. I cannot use public restrooms or locker rooms.

I encourage you to act on behalf of the millions of people who have already suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma, migraines, and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives. I would also like you to consider that your decision to acknowledge the misbranding of "Eternity" under your regulations and to require an appropriate warning label could prevent others particularly babies and children, from developing these disabling illnesses.

Please contact me if I can provide further information. I appreciate your consideration of this matter.

Yours truly,

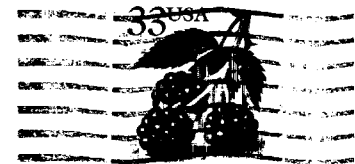
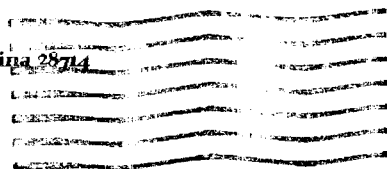
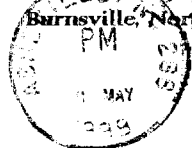
A handwritten signature in cursive script, appearing to read "Jacqueline F. Colson".

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